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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,136	07/28/2003	Ben A. Hitt	CORR-004/02US	4523

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Cooley Godward LLP
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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/628,136	Applicant(s) HITT ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006 and 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,16-18,20-22 and 27-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,16-18,20-22 and 27-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/6/06; 5/2/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response, filed 6 April 2006 and Supplemental response filed 2 May 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3-14, 16-18, 20-22, and 27-38 are currently pending. Claims 2, 15, 19, and 23-26 have been cancelled.

Information Disclosure Statements

The Information Disclosure Statements filed 6 April 2006 has been partially considered. References 77, 80, 86, 139, and 154 have not been considered, as they lack a publication date. The Information Disclosure Statement filed 2 May 2006 has been considered in full. Signed copies of PTO forms 1449 are included with this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is necessitated by amendment.

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Claims 28-25 are directed to methods of quality control for a bioassay that generates mass spectral data, which does not recite either a physical transformation of matter or a practical application [i.e. concrete, tangible, and useful result]. The instant claims recites steps comprising providing a location in n-dimensional space for a control and test sample, comparing the two, and determining error (claim 28) or displacement (claim 32). No description or definition for “providing” data or “comparing” centroids is provided in the specification such that these steps would be interpreted as physical steps. Therefore, the claimed method steps do not result in a physical transformation of matter. Where a claim does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. practical application). However, no actual concrete result is recited in the claims, nor is a useful result “produced” in a tangible form to one skilled in the art.

It is noted that independent claims 1, 12, 27, and 36 recite physical steps, such as diluting samples and performing mass spectrometry, and therefore, are considered statutory and not rejected herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-14, 16-18, 20-22, and 27-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection and is necessitated by amendment.*

Claims 1 and 12, as amended, recite, “the control model including at least one control centroid located in n-dimensional space defined by n mass spectral features included in the control model”. Applicant has failed to provide support for this limitation and none is apparent in the specification. The specification describes a “model’s centroid” at paragraph 0033 and a “predetermined hypervolume centered on the centroid” at paragraph 0031 and mapping “vectors” to n-dimensional space at paragraph 0033. However, there is no apparent teaching of a “control centroid” defined by n mass spectral features in the control model.

Further, claims 1 and 12, as amended, recite, “if the test spectrum maps to the n-dimensional space within an acceptable distance from the control centroid, submitting the test spectrum to the biological diagnostic”. Applicant has failed to provide support for and the specification fails to describe the “an acceptable distance from the control centroid” and “submitting the test spectrum to the biological diagnostic”.

Claim 27, as newly submitted, recites, “at least one control centroid associated with one diluent and that distinguishes the one diluent from at least one second diluent”. Applicant has failed to provide support and none is apparent for this claim limitation. The specification does not describe a control centroid in association with a diluent.

Claims 28 and 32, as newly submitted, recite, “at least one control centroid associated with a preferred diluent concentration and composition”. Applicant has failed to provide support

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and none is apparent for this claim limitation. The specification does not describe a control centroid in associated with a preferred diluent.

Claim 36, as newly submitted, recites, “the control model including at least one control centroid located in n-dimensional space defined by n mass spectral features included in the control model”. Applicant has failed to provide support for this limitation and none is apparent in the specification. The specification describes a “model’s centroid” at paragraph 0033 and a “predetermined hypervolume centered on the centroid” at paragraph 0031 and mapping “vectors” to n-dimensional space at paragraph 0033. However, there is no apparent teaching of a “control centroid” defined by n mass spectral features in the control model.

In conclusion, all claims are rejected as containing New Matter. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-14, 16-18, 20-22, and 27, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *This rejection is necessitated by amendment.*

Claims 1, 12, and 36 as amended or newly added, recite, “the control model including at least one control centroid located in an n-dimensional space defined by n mass spectral features included in the control model”. It is unclear whether it is the “space” that is “defined by n mass spectral features” or if it is the “control centroid” that is “defined by n mass spectral features”. It

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is further unclear whether the space is “included in the control model” or if it is the control centroid that is included in the control model. Clarification is requested.

Claim 1, as amended, recites, “mapping the test spectrum obtained from said performing to the n-dimensional space”. It is unclear if this intended to be the n-dimensional space of the control model or of the control centroid. Clarification is requested through clearer claim language.

Claim 27 recites, “providing in an n-dimensional space...one diluent and that distinguishes the one diluent from at least one second diluent...using an eletrospray...ionizing a test serum diluted with a test diluent...mapping the test map spectrum to n-dimensional space.” It is unclear if the test diluent of the “using step” is the same or different from the diluent of the “providing step” and how these two steps relate to one another to map a test spectrum. Clarification is requested.

Conclusion

No claims are allowed.

The outstanding rejections under 35 USC 101 for lack of utility have been withdrawn in view of the amendments to the claims.

The outstanding rejections under 35 USC 102(a) over Petricoin have been withdrawn in view of the Interview of 4 April 2006. Petricoin does not teach a quality assurance method with a control model including control centroids.

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The outstanding rejections under 35 USC 102(b) over Adam have been withdrawn in view of the Interview of 4 April 2006. Adam does not teach a quality assurance method with a control model including control centroids

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 14, 2007

Lori A. Clow, Ph.D.

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Lori A. Clow

Patent Examiner